REMARKS/ARGUMENTS

Claims 18-26, 28-30, 32-51, 53-55 and 57-62 are pending. Independent Claim 18 has been revised to more clearly refer to the peel strength of the claimed tubes. The Applicants submit that this claim already adequately characterizes the peel strength of the claimed tubes by reference to JIS K6854. However, support for the additional clarifications is found on page 17, first paragraph, of the specification. The claim set has been generally amended for clarity and include various editorial revisions and deletions. Accordingly, the Applicants do not believe that any new matter has been added. Favorable consideration is now respectfully requested.

Rejection—35 U.S.C. 112, first paragraph

Claim 43 was rejected under 35 U.S.C. 112, first paragraph, as lacking adequate description. The Applicants submit that this rejection may be withdrawn in view of the revision of this claim to refer to an inner layer containing 70 to 100 mass% of the polypropylene resin, which is described in the specification at page 10, line 2, of the specification.

Rejection—35 U.S.C. 112, second paragraph

Claims 18-62 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. These rejections are moot in view of the amendment of these claims.

Rejection—35 U.S.C. 102

Claims 18-20, 22-36, 41-43 and 45-58 were rejected under 35 U.S.C.102(b) as being anticipated by Kodama et al., JP 09-254339. The Applicants submit that this rejection may be withdrawn for several reasons discussed in detail below. Briefly, Kodama is directed to

very thin films and not to a tube. For example, the cited English abstract of this document does not mention a tube. Moreover, to further distinguish the invention from Kodama, independent Claim 18 has been revised to further elaborate on the physical characteristics, such as tube/tube shear peel strength below 35N and the tube/film 180° peel strength of less than 10N.

Comparison of present invention with Kodama et al.

(1) The present invention is directed to a tube.

The present invention is directed to a tube that is hollow inside, and forming a channel through which a fluid may flow. More specifically, the present invention is directed to a multi-layered tube suitable for use in an extracorporeal circulation circuit such as a blood circuit for artificial kidney dialysis, a blood circuit for blood plasma exchange, a circuit for ascites treatment systems by filtration, concentration and infusion. The multi-layered tube of the present invention is also preferably used in various medical devices such as a blood tube, an infusion tube, a catheter and a balloon catheter, etc.

The tube for such medical apparatuses must hold intact its tubular-shape and not be deformed or crashed easily under its own weight (shape-sustainability), thereby securing said tube's inside channel so that blood or infusion fluid can run through the channel smoothly. In order to have enough shape-sustainability, a tube should have some rigidity, which means that said tube is composed of thick plastic sheet to give good tube-wall thickness. In the present invention, the thickness of the tube is about 1.0 mm to 1.1 mm (1,000μm-1,100μm) (see p21, lines 33-36, p29, lines 1-6, of the specification).

(2) Kodama et al. is directed to a film

Kodama et al. is basically directed to a film (a very thin film), not a tube. More specifically, Kodama et al. is substantially directed to a wrapping film for apparel materials, film for book cover, film for electronic circuit printing, wrapping film for stationery products,

wrapping film for medical appliances, medical disposable bag, medical and sanitary material, facial film, and surface protection film and the like (see paragraph [0026] of Kodama et al. publication). The film disclosed in Kodama et al. has the thickness of not less than 10μm, preferably 20μm, and in the preferred embodiment example, 40μm thick multi-layered film is used (see paragraph [0012] and [0014] of Kodama et al. publication).

Considering the thickness of the film (10μm, 20μm, 40μm) to which Kodama et al. is directed to, it is undoubtedly to be used as a wrapping film only, such as well known Saran Wrap™ wrapping film (its thickness is about 10-20μm). It goes without saying that such a thin film like Saran Wrap ™ can not make a practical tube. Because the tube made of such thin film has no shape-sustainability and easily deforms or collapse under its own weight, rendering its use for medical application such as blood infusion tube completely impossible.

The multi-layered tube of the present invention has a wall thickness of 1,000-1,100μm, about one hundred(100) times the thickness of Kodama et al.'s thin wrapping film (10-20μm). Accordingly, Kodama does not describe and thus cannot anticipate the tubes of the present invention.

(3) Comparison.

As described above, the tube of the present invention and film of the Kodama et al. are both directed to multi-layered body, but the basic shapes ("tube" versus "film") are completely different. The different structural characteristics of the prior art film and claimed tube provide different utilities and solve different problems. The tube of the present invention with form-sustainability, having a hollow channel formed inside, is suitable for use in medical appliance, and is assembled to make a blood circuit line, thereby supplied blood or fusion fluid to the line flows through the channel. While conventional medical tube, which is composed of flexible plastic material, has a drawback wherein the tube tends to sometimes

deform during handling, especially when being bent, causing kinks to form. Said kinking, when it occurs in a tube, can clog the channel, thereby blocking the smooth stream of blood or fusion fluid, rendering the tube inapplicable for medical applications. In addition, since the tube of the present invention is directed to medical use with blood or infusion fluid flowing through inside channel, no plasticizer contained in the tube is allowed to dissolve out and pollute blood stream and the like.

On the contrary, Kodama et al. is directed to a thin film, not a tube. The film is mainly used for wrapping applications, not for flowing blood and the like. In addition, because the film of Kodama et al. is so thin that it cannot make a form-sustainable tube, as already discussed. In short, there is no occurrence of kinking to the wrapping film of Kodama et al., which forms a remarkable and striking contrast with the tube of the present invention.

(4) The word "tube" is not found in Kodama et al.

A. The Official Action suggests that the Abstract and Paragraph 26 [0026] of Kodama et al. anticipate a "tube" (page 5, lines 4-10, paragraph 10), however, this appears to be incorrect. The Applicants have conducted a though, and word-to-word study of the indicated parts pointed to with meticulous attention and came to a conclusion that there is not a single word corresponding to "tube" to be found in the description of the Abstract and "Paragraph 26 [0026]" of Kodama et al. For the convenience of the Examiner, as exhibits, the Applicants submit the English Abstract supplied by European Patent Office (EPO), a copy of the Japanese document with the key Japanese terms highlighted in paragraph [0226], as well as a current machine-translation of this document in English.

The Examiner attention is now directed to paragraph [0226] of the Japanese document. In Japanese, the word "tube" is expressed as チューブ in Japanese Kana-Moji

(Kana-letters). The Japanese word for "film" is expressed as フィルム. The Applicants invite the Examiner to review paragraph [0026] to determine whether the Japanese term for "tube" is present in this paragraph. The attached machine-translation of this document also shows that paragraph [0026] only refers to "films".

B. That Kodama et al. disclose only a "film", not tube, is also shown clearly from the following descriptions of the Applicants' specification and Kodama et al.'s original Japanese publication text:

In the multi-layered tube of the present invention, the ratio of the thickness of substrate layer (I) to that of connection layer (II) is 940-980/60-50(=16/1-49/1), indicating that the substrate layer (I) should be thick enough compared with connection layer (II), or in other words, the connection layer (II) should be thick enough compared with substrate layer (I). Please refer to Fig. 1, showing diagrammatically that thickness of layer (I) is much larger than that of layer (II).

If the thickness ratio of layer (I) to layer (II) is not within said specified value, the tube comes to lose flexibility and especially, kinking phenomenon, which is critical for use in any medical application like blood transfusion, may occur.

On the other hand, in the Kodama et al. film, the ratio of substrate layer to surface layer is 1/1-8/1, preferably 2/1-6/1 (see Paragraph [0012]), indicating that the thickness of substrate layer to facial layer is too small that if a tube is to be made using this film, the obtained tube has no shape-sustainability and readily deform or collapse under its own weight.

(5) In the Kodama et al. film, it is stated that a block copolymer is not suitable for wrapping use and should be excluded from the resin composition to form multi-layered film. Kodama et al. teach a hydrogenated diene-based polymer composed of a conjugated diene compound and aromatic vinyl compound which is to be hydrogenated, and this compound is

composed of mainly random copolymer. With this point, the Kodama et al. copolymer multi-layered film is completely different from present invention wherein substantially only block copolymer is used and random copolymer is excluded.

However, in the paragraph [0007] of Kodama et al., it is allowed that within said polymer molecular chain, some part of polymer block could be included. In that case, the amount of said polymer-block in the polymer before hydrogenation, is preferably not more than 50 wt%, more preferably not more than 40 wt%, even more preferably not more than 30 wt.%. If the amount of polymer-block exceed 50 wt.%, the obtained multi-layered film shows the tendency to lose transparency, flexibility and low temperature resistance, so it is stated that the use of polymer-block (especially such block copolymer as used in the present invention whose polymer block content being 100 mass%, with random copolymer content being 0 mass%) should not be used in the Kodama et al.

More specifically, in Comparative example 3, Kodama et al. disclose a substrate layer containing 20% of block copolymer (styrene-butadiene-styrene block copolymer) and surface layer containing 7.5% of block copolymer (styrene-butadiene-styrene block copolymer) to form a three layered film. But the obtained film lacks transparency, flexibility, and cannot be used as wrapping film (see paragraph 25 [0025], table 3). That is, for the purpose of wrapping application, it is concluded that the use of block copolymer should be avoided.

On the contrary, in the present invention, block copolymer (zero random copolymer content) is most preferably used, especially, the thick substrate layer should contain great amount of block copolymer as high as 60-95 mass% which is far beyond the predicted value from Kodama et al., thereby providing a multi-layered tube suitably for use in medical application such as forming a blood or infusion circuit.

Accordingly, as Kodama et al. do not disclose or suggest the tube of the present invention, the Applicants respectfully request that this rejection now be withdrawn.

Rejection—35 U.S.C. 103

Claims 21 and 44 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al., JP 09-254339. The Applicants submit that this rejection may also be withdrawn, because Kodama does not disclose or suggest the tube of the present invention. Please see the remarks above in response to the anticipation rejection.

Rejection—35 U.S.C. 103

Claims 37-40 and 59-62 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama et al., JP 09-254339. The Applicants submit that this rejection may also be withdrawn, because Kodama does not disclose, suggest nor provide a reasonable expectation of success for the tube of the present invention. Please see the remarks above in response to the anticipation rejection.

Rejection—35 U.S.C. 103

Claims 18-31, 35, 37-45 and 49-62 were rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al., U.S. Patent No. 5,928,744, in view of Strassmann, U.S. Patent No. 6,127,009. The Applicants submit that the cited prior art does not disclose or suggest the claimed invention for the following reasons.

Heilmann et al. is concerned with a multilayer tube which appears to resemble that of the present invention. However, the multilayer tube of Heilmann et al. has a characteristic feature in that a connection layer B made of a plastic material that is dimensionally unstable at a temperature of <121°C during autoclave sterilization is laminated on a base layer A. The connection layer B that is thermally unstable and meltable (fusible) is purposely employed so that the connection layer H can be fused of melted and bonded to other medical article such

as a medical bag or connector during autoclave sterilization. As a plastic material for constituting the connection layer B, the Heilmann tube does not use any general polyethylene resin, but uses a special resin. For instance, as such special resins, the Heilmann specifically describes 100% SEBS (styrene/ethylene/butylene/stylene rubber), 100% SEPS (stylene/ethylene/propylene/stylene rubber)% and a blend of 50-100% PE-copolymer (polyethylene copolymer) and 0-50% EBS(styrene/ethylene/butylene/stylene rubber)/SEB(stylene/ethylene/ butylene rubber).

It should be noted that the above special resins are rubbery materials that are softened to flow at 121°C. The mere use of any general polyethylene resin is not sufficient for accomplishing the object of the Heilmann invention. For example, "PE copolymer" described in the Heilmann is a commercial product called "Engage" supplied by Dow Chemicals. "Engage" is an elastomer of an ethylene octane copolymer and has a melting temperature of as low as approximately 30-105°C, and it is fundamentally different from any general polyethylene resin. In the multilayer tube of Heilmann, the connection layer (B) is positioned as an outermost layer and/or innermost layer. The Heilmann tubing therefore suffers from the following problems:

(i) when the connection layer (B) is an outermost layer, the outermost layer is melted (fused) during sterilization, and the multilayer tube may be bonded to a sterilization bag that is in contact with the outermost layer.

(ii) when the connection layer (B) is an innermost layer, the multilayer tube has poor durability against forceps since the connection layer (B) has adhesion properties (When the forceps is removed from the tube after the tube is closed with the forceps, no through path is easily formed or recovered inside the tube.).

Comparison of the present invention with the Heilmann, et al. invention. The Heilmann tubing has the above-mentioned defects, while the present invention has no such defects. That is because both the first substrate layer (I) and the connection layer (II) in the present invention are constituted of resin compositions containing the (b) specific hydrogenated (block) copolymer dimensionally stable at 121°C and a (a) thermally stable polypropylene resin. Therefore, the multi-layered tube of the present invention does not have any sticking nature on the surface when sterilized at 121°C in an autoclave and it can retain proper flexibility without having kinking properties or tendency toward bending when the tube is bent.

Table 1 (see next page) compares the multilayered tube of the present invention and the multilayer tube of the Heilmann et al. invention. As is clear from Table 1, the present invention and the Heilmann et al. invention basically differ from each other as to whether or not the connection layer dimensionally stable at 121°C is present. This difference is essential. That is, the multi-layered tube of the present invention is completely different from the counterpart of the Heilmann et al. invention.

Table 1

	Multi-layered tube of the invention (two layers)	Multi-layered tube of the invention (three layers)	Multilayer tube of Heilmann et al patent (three layers)
↑ Inner layer	First substrate layer (I): Dimensionally stable at 121°C (a) Polypropylene resin 5-40% (b) Hydrogenated (block) copolymer 95-60%	Second connection layer (II): Dimensionally stable at 121°C (a) Polypropylene resin 45-100% (b) Hydrogenated (block) copolymer 55-0%	Cover layer (protective layer) (C): PP-R 40-60% SIS 60-40%
Outer layer ↓	Second connection layer (II): Dimensionally stable at 121°C (a) Polypropylene resin 45-100% (b) Hydrogenated (block) copolymer 55-0%	First substrate layer (I): Dimensionally stable at 121°C (a) Polypropylene resin 5-40% (b) Hydrogenated (block) copolymer 95-60%	First base layer (base layer) (A): PP-R 0-50% SIS 100-50%
		Second connection layer (II): Dimensionally stable at 121°C (a) Polypropylene resin 45-100% (b) Hydrogenated (block) copolymer 55-0%	Second connection layere (B): Plastic material (rubbery material) dimensionally unstable at 121°C

The Strassmann invention relates to a medical bag and it is described that a crosslinked specific multilayer tube is used as a joining part for bonding a bag and a hard part, thereby to produce a multilayer bag of a polypropylene film as the above bag. It is described that an inner surface does not stick to itself in steam sterilization due to the use of polypropylene as a bag material, so that the bag can be safely heat-sterilized. Formerly, when polyethylene or PVC was used, it had to be roughened to prevent the inside faces from sticking together when the inner layer of the bag was PVC or polyethylene (column 4, lines 25 - 35). The roughening means the formation of a number of fine convexoconcave shapes on the surface, so that the transparency of the film decreases.

The Official Action indicates that since Strassmann describes that polypropylene is preferably used in making the tube rather than polyethylene, it is easier to substitute polypropylene for polyethylene forming the connection layer (B) in the Heilmann et al. invention. However, the Applicants submit that such a substitution would be technically meaningless within the context of the Heilmann invention. Therefore, as explained below the cited prior art would not suggest or motivate one with ordinary skill in the art to make such a substitution.

The Heilmann invention has a characteristic feature in purposely using, as the connection layer (B), a layer made of a plastic material that is dimensionally unstable during autoclave sterilization at 121°C, and the Heilmann et al. invention has a technical essence in this point. However, if thermally stable polypropylene is substituted for the polymer that is dimensionally unstable at 121°C, such as 50 - 100% PE-copolymer "Engage", the layer comes to be dimensionally stable at 121°C in autoclave sterilization, and the layer no longer works as the connection layer that is an essentially characteristic point. The connection layer is formed of a polymer that is dimensionally unstable at 121°C, so that the connection layer is

melted (fused) and can bond to other medical material such as a medical bag or connector during autoclave sterilization. Therefore, the above substitution would only disrupt and nullify the technical essence of the Heilmann et al. invention, and can be said to be meaningless in a technical sense.

The material for the connection layer (s) in the Heilmann invention cannot be simply bundled up as a polyethylene resin. As already explained, for the connection layer (B), the Heilmann invention purposely selects and uses a special rubbery material that is softened to flow at 121°C, such as 100% SEBS (styrene/ethylene/butylene/stylene rubber), 100% SEPS (stylene/ethylene/propylene/stylene rubber), or a blend of 50-100% PE-copolymer (polyethylene copolymer) and 0-50% SEBS(styrene/ethylene/butylene/styrene rubber)/SEB(stylene/ethylene/ butylene rubber).

Moreover, there is no motivation for substituting polypropylene for polyethylene in the Strassmann invention into the Heilmann invention. While the paragraph bridging pages 8 and 9 of the first Official Action, the Examiner states that "Substituting polypropylene for polyethylene ... the processing steps of roughening are avoided, and furthermore the tube has even better transparency". The Strassmann invention seeks to overcome the problem of roughening of a bag having a large inner area (that is a sheet-like object and not a tube). However, the multilayered tube of the Heilmann invention (and of the present invention) is a very small tube having an inner diameter of approximately 3 to 6 mm, and roughening of the inner surface of the tube having such a small inner diameter cannot be easily made at all.

While the Official Action opines that it is easy to substitute a polypropylene resin for a polyethylene resin for avoiding the unrealistic and unimaginable step of roughening the inner surface of a multi-layered tube having such a small diameter and improving the transparency. However, the Applicants submit that such a substitution would be unreasonable.

In this connection, the multi-layered tube of the present invention has high transparency not because a mere general polypropylene in the Strassmann is used, but because of the use of two layers made of plastic materials that are dimensionally stable at 121°C and contain (b) the specific hydrogenated (block) copolymer and (a) a thermally stable polypropylene resin. Accordingly, in view of the lack of suggestion in the cited art for the present invention, the Applicants respectfully request that this rejection be withdrawn.

Rejection—35 U.S.C. 103

Claims 32-34 and 46-48 were rejected under 35 U.S.C. 103(a) as being unpatentable over Heilmann et al., U.S. Patent No. 5,928,744, in view of Strassmann, U.S. Patent No. 6,127,009; and further in view of Takeuchi et al., U.S. Patent No. 5,264,488. The cited prior art does not render the present invention obvious for the following reasons. Heilmann and Strassmann do not disclose or suggest the present invention for the reasons discussed above.

Takeuchi et al. is concerned with a material for a medical bag and tube. The Takeuchi et al. reference discloses a material made of a composition comprising

(I) a polyolefin,

(II) a polybutadiene block, polybutadiene or vinyl aromatic compound-butadiene copolymer,

(III) at least one of

(i) a block copolymer comprised of a vinyl aromatic compound - conjugate diene compound block copolymer,

(ii) a vinyl aromatic compound - conjugated diene compound random copolymer, and

(iii) a hydrogenated block copolymer composed of a vinyl aromatic compound - conjugate diene compound block copolymer.

Further, the 1,2-vinyl bond content in the polybutadiene and the hydrogenation ratio of the polybutadiene are merely defined.

The Takeuchi et al. reference has no description that can suggest the formation of a multi-layered tube formed of a substrate layer (I) and a connection layer (II) that are made of resin compositions containing a specific hydrogenated (block) copolymer and a polypropylene resin, the content of the polypropylene resin being different between the substrate layer (I) and the connection layer (II) as specified in the present invention.

The Examiner states that the heat resistance in sterilization can be maintained by applying the hydrogenated block copolymer to the Heilmann at al. invention. However, the Heilmann et al. invention has its technical essence in the connection layer (II) made of a plastic material (rubbery material) that is dimensionally unstable at 121°C as shown in Table 2. Therefore, the present invention is not at all easily inferable from any combination of the Takeuchi et al. invention with the Heilmann et al. invention.

Further, from the viewpoint of materials, the materials of the Takeuchi et al. invention are not at all relevant to the material of the multi-layered tube of the present invention. That is, Takeuchi et al. describe nothing concerning a "hydrogenated block copolymer formed of a vinyl aromatic compound polymer block and an isoprene polymer block" recited in the present claim 10. Further, the Takeuchi et al. do not describe anything, either, concerning a "hydrogenated block copolymer formed of a vinyl aromatic compound polymer block and an isoprene and butadiene polymer block" recited in the present claim 11.

Takeuchi et al. describe a block copolymer (II) apparently similar to the block copolymer in the present claim 12. While the above block copolymer (II) always contains a polybutadiene block segment (C) having a 1,2-vinyl bond content of 20 % or less, the 1,2-vinyl bond content in the polybutadiene specified in the present claim 12 is at least 30 mol%, so that the block copolymer in the present claim 12 is entirely different from the block

copolymer (11) in Takeuchi et al. Accordingly, the Applicants respectfully submit that this rejection may now be withdrawn.

CONCLUSION

In view of the above amendments and remarks, the Applicants respectfully submit that this application is now in condition for allowance. Early notification to that effect is respectfully requested.

Respectfully submitted,

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